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L3 and (water adj1 insoluble)	12

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<u>L4</u>	L3 and (water adj1 insoluble)	12	<u>L4</u>
<u>L3</u>	(enteric adj5 suspension)	110	<u>L3</u>
<u>L2</u>	(enteric adj5 suspension) and (polyvinyl adj1 alcohol)	11	<u>L2</u>
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L2: Entry 9 of 11

File: USPT

Mar 10, 1998

DOCUMENT-IDENTIFIER: US 5725852 A

TITLE: Transmucosal therapeutic composition

Detailed Description Text (62):

The base for the transmucosal therapeutic composition of the present invention may be a hydrophilic compound having a capacity to disperse the peptide and said additives. The molecular weight of such hydrophilic compound is not less than 1000, preferably not less than 10000 and more preferably not less than 100000. The compound need only be a pharmaceutically acceptable substance and typically includes but is not limited to the following compounds. Thus, copolymers of polycarboxylic acids or salts thereof or carboxylic anhydrides (e.g. maleic anhydride) with other monomers (e.g. methyl (meth)acrylate, acrylic acid, etc.), hydrophilic vinyl polymers such as polyvinyl acetate, polyvinyl alcohol, polyvinylpyrrolidone, etc., cellulose derivatives such as hydroxymethylcellulose, hydroxypropylcellulose, etc., and natural polymers such as chitosan, collagen, sodium alginate, gelatin, hyaluronic acid, etc. and nontoxic metal salts thereof. Further, synthetic fatty acid esters such as polyglycerin fatty acid esters, sucrose fatty acid esters, etc. can also be mentioned.

Detailed Description Text (76):

When the dosage form is a rectal suppository, it is inserted from the anus with fingers. The vaginal suppository is inserted into the vagina with fingers or a pertinent applicator. For oral administration of nanocapsules, they are packed into a conventional gelatin capsule shell for oral administration. It is also possible to utilize a drug delivery system such that an enteric coating is applied to said gelatin capsule to cause the nanocapsules to be released only in the duodenum or inferiorly thereof, not in the stomach. It is also possible to add a liquid for oral administration, for example an isotonic saline solution or a syrup, to the above nanocapsules either as they are or as carrying an enteric coating and administer the resulting suspension.

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L2: Entry 11 of 11

File: USPT

Jan 9, 1996

DOCUMENT-IDENTIFIER: US 5482706 A

TITLE: Transmucosal therapeutic composition

Detailed Description Text (65):

The base for the transmucosal therapeutic composition of the present invention may be a hydrophilic compound having a capacity to disperse the peptide and said additives. The molecular weight of such hydrophilic compound is not less than 1000, preferably not less than 10000 and more preferably not less than 100000. The compound need only be a pharmaceutically acceptable substance and typically includes but is not limited to the following compounds. Thus, copolymers of polycarboxylic acids or salts thereof or carboxylic anhydrides (e.g. maleic anhydride) with other monomers (e.g. methyl (meth)acrylate, acrylic acid, etc.), hydrophilic vinyl polymers such as polyvinyl acetate, polyvinyl alcohol, polyvinylpyrrolidone, etc., cellulose derivatives such as hydroxymethylcellulose, hydroxypropylcellulose, etc., and natural polymers such as chitosan, collagen, sodium alginate, gelatin, hyaluronic acid, etc. and nontoxic metal salts thereof. Further, synthetic fatty acid esters such as polyglycerin fatty acid esters, sucrose fatty acid esters, etc. can also be mentioned.

Detailed Description Text (80):

When the dosage form is a rectal suppository, it is inserted into the anus with fingers. The vaginal suppository is inserted into the vagina with fingers or a pertinent applicator. For oral administration of nanocapsules, they are packed into a conventional gelatin capsule shell for oral administration. It is also possible to utilize a drug delivery system such that an enteric coating is applied to said gelatin capsule to cause the nanocapsules to be released only in the duodenum or interiorly thereof, not in the stomach. It is also possible to add a liquid for oral administration, for example an isotonic saline solution or a syrup, to the above nanocapsules either as they are or as carrying an enteric coating and administer the resulting suspension.

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L1 and micro\$	50

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<u>L3</u>	L1 and micro\$	50	<u>L3</u>
<u>L2</u>	L1 and nano\$	0	<u>L2</u>
<u>L1</u>	enteric\$ adj3 suspension	78	<u>L1</u>

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L1: Entry 33 of 78

File: USPT

Sep 7, 1999

DOCUMENT-IDENTIFIER: US 5948773 A

**** See image for Certificate of Correction ****

TITLE: Formulation comprising antibacterial substance and antiulcer substance

Detailed Description Text (40):

Sugar spheres was coated with a mixture of lansoprazole, magnesium carbonate, sucrose, starch and L-HPC-31 by means of spraying aqueous HPC-L solution in a centrifugal fluid-bed granulator (CF-1000S, Freund Co.), and the resultant wet granules were dried in a vacuum oven at about 40.degree. C. for about 18 hours, and then sieved. The obtained granules were coated with aqueous enteric Eudragit suspension containing PEG-6000, talc, titanium dioxide and Rheodol TW-0120 in a fluid-bed coater (F10-Coater FLO-60, Freund Co.), and sieved, and then dried in a vacuum oven at about 42.degree. C. for about 18 hours. The obtained granules were mixed with talc and Aerosil.

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L3: Entry 42 of 50

File: USPT

Jun 7, 1994

DOCUMENT-IDENTIFIER: US 5318781 A

TITLE: Absorption enhancement of antibiotics

Brief Summary Text (36):

The terms "antibacterial" and "antibiotic" are used interchangeably throughout this disclosure to refer to bactericidal or bacteriostatic compounds which have been metabolically derived from a microorganism, synthetically prepared by chemical means, or prepared by a combination of microbial and chemical procedures (semi-synthetic).

Brief Summary Text (68):

The inventive compositions are in the form of an enteric coated liquid suspension dosage form. The formulation can be filled into a hard or soft-shell capsule or their equivalent and the capsule is coated with the enteric coating in accordance with conventional techniques.

Detailed Description Text (11):

The plates were incubated overnight at 37.degree. C. and the zones of inhibition were read to the nearest 0.1 mm. Calculations of C.sub.max and C.sub.max Ranges were made using an autoassay machine (Giles Scientific, Inc., New York). For reference, see J. V. Bennett et al., Applied Microbiology 14, 170-177 (1966).

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L3: Entry 45 of 50

File: USPT

Jan 23, 1990

DOCUMENT-IDENTIFIER: US 4895725 A

TITLE: Microencapsulation of fish oil

Abstract Text (1):

Microcapsules containing oil-based biologically active compounds which are stable over extended time periods for release of the encapsulated compound in the intestine. There are a number of biologically active compounds having an oil base which must be orally ingested in order to have a beneficial effect. An example of one such biologically active oil-based compound is a fish oil having a high content of polyunsaturated omega-3 fatty acids which has been demonstrated to reduce plasma levels of triglycerides, very low density lipoprotein, low density lipoproteins and cholesterol in normal and hyperlipidemic subjects. The disclosed microcapsules eliminate the unfortunate problems of the unpleasant taste and smell of the fish oil, as well as the aftertaste, particularly when ingested in large quantities, and provide a palatable and practical means of ingesting efficacious quantities of fish oil. In addition, the normal oxidation of polyunsaturated fatty acids is inhibited.

Brief Summary Text (2):

This invention relates to tasteless, odorless, palatable fish oil-containing microcapsules.

Brief Summary Text (3):

As described in U.S. Ser. No. 088,651, the fish oil is encapsulated using conventional procedures within microcapsules formed of compounds such as gelatin and gelatin-acacia which are unstable in both the stomach and gastrointestinal tract. The microcapsules are then blended with a vegetable oil, such as peanut oil, that is immiscible with water. Although the microcapsules alone are unable to eliminate the odor and taste of the fish oil, the combination of the vegetable oil juxtaposed with the microcapsule enables one to completely mask the odor and taste of the oil.

Brief Summary Text (6):

Other materials have been used to encapsulate oils. One method for encapsulation of oil is disclosed by British Pat. 1,236,885 to Fuji Photo Film Company, Ltd. This patent describes a method for preparing multiwall microcapsules containing oil where the wall film consists of a complex coacervate of gelatin and gum arabic. The microcapsules are dispersed in a water soluble high molecular film-forming material which is precipitated by addition to an aqueous solution containing hydroxyl, acid or basic groups and hardened by addition to a solution containing positive ions such as calcium. This is a complicated and inconvenient procedure, however, and does not prevent the aftertaste caused by belching up oil released in the stomach.

Brief Summary Text (13):

Fish oil-containing microcapsules suitable for incorporation into a variety of aqueous based and dry food products such as gelatin, orange juice and yogurt are prepared by encapsulating fish oil within an enteric coating such as ethyl cellulose.

Brief Summary Text (14):

The microcapsule are formulated from an emulsion of fish oil and enteric coating suspended in a basic solution, preferably a 25% suspension of ethyl cellulose in ammonium hydroxide. The emulsion is atomized into an acidic solution using an inert gas such as nitrogen or argon. The resulting microcapsules are filtered out of the acidic solution, washed with water and a surfactant and dried. The conditions under which the emulsion is atomized determines the particle size, which can range from about 0.1 to 500 microns, preferably between about 0.5 to 100 microns.

Brief Summary Text (15):

The fish oil microcapsules are odorless, tasteless, and have a smooth, creamy consistency when made under the preferred conditions. The encapsulated fish oil is stable both at room temperature and at 4.degree. C., in the presence of light, and when incorporated into a variety of food products. The enteric coating disintegrates under neutral and basic conditions, as when the microcapsules are ingested and reach the intestine.

Brief Summary Text (19):

In addition to fish oil, a variety of oil-based bioactive materials can be encapsulated and ingested according to the method of microcapsulation of the present invention. For example, other fish oils such as cod liver oil, mineral oil, oil-soluble vitamins and drugs which are delivered in an oil base, can be incorporated into the microcapsules. An example of a drug which is normally delivered orally in an oil base within a capsule is cyclosporin, an immunosuppressant which must be taken on a long-term basis to avoid graft rejection or to treat other autoimmune disease.

Detailed Description Text (2):

Preparation of Microcapsules Within an Alginatecellulose acetate capsule

Detailed Description Text (3):

Microcapsules having diameters of between 2 microns and 1 millimeter were prepared from an emulsion of alginate and oil precipitated by addition to a solution containing calcium. The oil-containing microcapsules were then resuspended in a basic solution of an enteric coating, cellulose acetate phthalate, which was precipitated around the alginate-walled microcapsules by addition of the cellulose acetate phthalate in a basic solution into an acid solution.

Detailed Description Text (4):

Although the microcapsules containing the fish oil initially did not have either an unpleasant taste or odor, these microcapsules were not stable over time.

Detailed Description Text (7):

As emulsion of 20 parts commercially obtained fish oil, such as fish oil rich in polyunsaturated omega-3 fatty acids sold under the trademark MAX EPA by Seven Seas Health Care Ltd., Marfleet, Hull, U.K. or fish oil sold under the trademark SAN OMEGA by Nippon Oil & Fats Co., 10-1 Yuraku-cho, 1 Chome, Chiyoda-ku, Tokyo, Japan, and 80 parts of a 25% suspension of ethyl cellulose in ammonium hydroxide was prepared under nitrogen. The emulsion was atomized using a nitrogen stream into a stirred solution of glacial acetic acid in water (50:1000). Oil-containing microcapsules were formed in the acetic acid solution. These were filtered, washed extensively with water, washed with 0.5% Tween 20, and washed extensively with water. The microcapsules were dried.

Detailed Description Text (8):

These microcapsules were stable both at room temperature in light and at 4.degree. C. for an extended period of time. In contrast to the microcapsules formed in Example 1 which turned rancid after about three days, these microcapsules were still stable after more than one month.

Detailed Description Text (11):

Although glacial acetic acid is preferred, any other acid FDA approved for ingestion such as citric acid, lactic acid, malic acid, ascorbic acid, or phosphoric acid could be utilized. The relative volume of the enteric coating suspension to the acidic solution may be adjusted as required to obtain the desired size and quantity of microcapsules. In general, the volume should be sufficient to provide adequate stirring and to provide a clear surface for contacting the enteric coating-fish oil emulsion onto. A dispersing agent, such as starch, silica or kaolin, may be added to the enteric coating-oil emulsion or suspension, before or after atomizing.

Detailed Description Text (13):

The particle size is adjusted by varying the nozzle diameter and pressure of the atomizer. Inert gases such as argon or helium can be substituted for nitrogen. In the above example, a modified air brush was used to atomize the oil-enteric coating suspension. Particle size can vary between 0.1 and about 500 microns. The smaller size particles have a creamier consistency but lower loading capacity than the larger diameter particles. For example, particles having diameters of between about 0.1 and 1 micron have a consistency like butter. Microcapsules having a diameter of approximately 100 microns have a consistency of approximately that of cream cheese. In contrast, particles of greater than approximately 250 microns have a grainy texture. The preferred range is generally between about 0.5 and 250 microns.

Detailed Description Text (14):

Apparatus for forming and removing the microcapsules in the acidic solution are known to those skilled in the art, as are other methods of removing and washing the microcapsules.

Detailed Description Text (16):

Preparation of Fish Oil Microcapsule-Containing Food

Detailed Description Text (17):

Capsules prepared according to Example 1 were not stable over a period of more than three days and when incorporated into a variety of foods were found to have an objectionable taste and odor. In contrast, the microcapsules formed in Example 2 were mixed with flavored gelatin, orange juice, agar gel flavored with raspberry syrup and citric acid, yogurt and peanut butter, without subsequent degradation of the enteric coating. No objectionable taste or odor was observed over a period of more than three weeks.

Detailed Description Text (18):

In general, these microcapsules can be incorporated into any aqueous, oil-based or dry food product having a pH of about less than 7 or less than the pH at which the enteric coating dissolves. Particle size can be varied to produce the desired consistency.

Detailed Description Text (19):

Modifications and variations of the present invention, a method for forming fish oil-containing microcapsules having no objectionable taste or odor for subsequent incorporation into foods, will be obvious to those skilled in the art from the foregoing detailed description of the invention. Such modifications and variations are intended to come within the scope of the following claims:

Other Reference Publication (1):

Madan and Shanbhag, "Cellulose Acetate Phthalate Microcapsules: Method of Preparation", Communications, J. Pharm. Pharmac., 30, 65 (1978).

CLAIMS:

1. Palatable microcapsules comprising a biologically active material and an oxidizable oil having a strong odor and taste encapsulated within a non-oil soluble

enteric coating to form microcapsules having no taste or smell derived from the oil, said coating formed by preparing an emulsion of an oil-based biologically active compound and a non-oil soluble enteric coating in a basic solution, atomizing the emulsion into an acidic aqueous solution, and separating the precipitated microcapsules from the acidic aqueous solution.

2. The microcapsules of claim 1 wherein said oil-based biologically active material is fish oil containing polyunsaturated omega-3 fatty acids.

3. The microcapsules of claim 1 wherein said enteric coating is a cellulose derivative.

4. The microcapsules of claim 3 wherein said enteric coating is selected from the group consisting of ethyl cellulose, cellulose acetate trimellitate, and cellulose acetate phthalate.

5. The microcapsules of claim 1 wherein said microcapsules have a diameter of between approximately 0.1 and 500 microns.

6. The microcapsules of claim 5 wherein said microcapsules have a diameter of between approximately 0.5 and 250 microns.

7. The microcapsules of claim 1 wherein the enteric coating and the biologically active oil-based compound are in a ratio of between approximately 1:0.5 to 1:10.

8. The microcapsules of claim 1 wherein said microcapsules are formed by preparing an emulsion of the oil-based biologically active compound and enteric coating in a basic aqueous solution and atomizing the emulsion into an acidic solution.

9. The microcapsules of claim 1 blended with an edible food product having a pH of less than the pH at which the enteric coating dissolves.

10. A method for preparing edible microcapsules containing a biologically active compound and an oxidizable oil having a strong odor and taste comprising

preparing an emulsion of an oil-based biologically active compound and a non-oil soluble enteric coating in a basic solution,

atomizing the emulsion into an acidic aqueous solution to precipitate the enteric coating around the oil-based biologically active compound to form microcapsules having no taste or smell derived from the oil, and

removing the precipitated microcapsules from the acidic solution.

16. The method of claim 10 further comprising washing the microcapsules with a surfactant.

17. The method of claim 10 further comprising mixing the microcapsules with a food having a pH less than the pH at which the enteric coating dissolves.

20. The method of claim 10 wherein the emulsion is precipitated to form microcapsules having a diameter of between approximately 0.1 and 500 microns.

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